United States Court of Federal Claims

No. 03-295 V
Filed Under Seal: June 07, 2011
(Reissued: June 22, 2011)[*]

Tonya L. Jarvis,

Petitioner,

v.

Secretary of the Department of Health and Human Services,

Respondent.

Vaccine Act; Off-Table Claim; Motion for Review; Reliability of Expert Testimony; *Daubert*; Causation in Fact; Proof of Injury as Prerequisite to Proof of Causation

Clifford J. Shoemaker, Shoemaker & Associates, Vienna, VA, for petitioner.

Melonie J. McCall, Vaccine/Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for respondent.

OPINION *and* ORDER

Block, *Judge*.

Petitioner, Tonya L. Jarvis, alleges that she suffered a neurological injury[1] as a result of a hepatitis B vaccination that she received on October 2, 2000. *See Jarvis v. Sec'y of Health & Human Servs.*, No. 03-295V, 2010 WL 5601960, at *1, 3–7, 9–11 (Fed. Cl. Nov. 8, 2010). In 2003, Jarvis filed a timely petition with the Office of the Special Masters, seeking compensation under the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-1–300aa-34 (1994 & Supp. I 1995)) ("Vaccine Act"). *Jarvis*, 2010 WL 5601960, at *1.

[*] This opinion originally was issued under seal on June 7, 2011. Pursuant to Rule 18(b) of the Vaccine Rules of the United States Court of Federal Claims ("Vaccine Rules"), the parties had 14 days within which to propose redactions to the opinion prior to its publication, but no such redactions were proposed. Accordingly, the opinion is herein reissued for publication, unsealed.

[1] The petition alleges "a RHEUMATOLOGICAL/SKELETAL injury, specifically, Arthralgias (Joint Pain)." *Jarvis*, 2010 WL 5601960, at *1 (citing Pet. ¶¶ 5–6). However, virtually all of petitioner's proffered evidence—including her medical records and the testimony of petitioner's expert witness—focuses on attempting to demonstrate that she suffered a neurological injury, specifically, an inflammatory process that allegedly affected petitioner's brain and/or spinal cord, leading to her alleged symptoms of pain, loss of sensation, and muscle weakness. *See id.* at *3–7, 9–11.

After holding two evidentiary hearings, *id.* at *2, Chief Special Master[2] Campbell-Smith concluded that petitioner was not entitled to compensation because she had "not established that she suffered a vaccine-related injury," *id.* at *17. Before the court is petitioner's motion for review of the Chief Special Master's decision, wherein petitioner asks the court to set aside the Chief Special Master's decision and to enter judgment in petitioner's favor. *See* Pet'r's Mot. for Review at 17 ("Mot. for Review"). Petitioner's memorandum in support of this motion lists only one numbered objection, namely, that the Chief Special Master applied an elevated standard of proof that was contrary to law. *Id.* at 2; *see* Vaccine Rule 24(a) (requiring a petitioner's motion for review to "be accompanied by a memorandum of numbered objections" to the Special Master's decision). Specifically, petitioner argues that the Chief Special Master improperly required petitioner's key expert to substantiate his testimony to a degree of scientific certainty. *Id.*

For the reasons explained below, the court disagrees and concludes that the Chief Special Master lawfully discounted the testimony of petitioner's expert, testimony that was not supported by any objective indicia of reliability. Beyond this, the court concludes that the Chief Special Master's decision rested squarely upon petitioner's failure to make the threshold showing that she in fact suffered the injury for which she seeks compensation. Because this finding was all but inescapable in view of the record as a whole, the court affirms the Chief Special Master's decision and dismisses the petition.

I. BACKGROUND[3]

A. Petitioner's Medical History

In 2000, petitioner accepted employment as a day care provider at Walter Reed Child Development Center. *Jarvis*, 2010 WL 5601960, at *3. At the time, petitioner was thirty years of age and generally in good health, except for a history of allergic reaction (with symptoms including hives, headaches, and tongue swelling) to various medications. *Id.* As a condition of her employment, petitioner was required to receive vaccinations against polio and hepatitis B. *Id.* The vaccines were administered in two doses, the first on August 30, 2000, and the second on October 2, 2000. *Id.*

Two days after her second vaccination, petitioner presented to Dr. John Moore, at Walter Reed Army Medical Center, with a "malar rash" (a rash on her cheeks) and complaints of tingling in her face and along the left side of her body. *Id.* at *4; Hr'g Tr. at 15–16 (July 22, 2009). Petitioner reported to Dr. Moore that she became feverish and delirious within one hour of receiving her second vaccination. *Jarvis*, 2010 WL 5601960, at *4. Blood testing revealed slightly elevated levels of bilirubin (a possible indication of liver problems or inflammation of red

[2] On April 7, 2011, Patricia Campbell-Smith, then a Special Master, was elevated to the position of Chief Special Master. U.S. Court of Federal Claims, *Chief Judge Hewitt Announces Special Master Campbell-Smith as Chief Special Master*, http://www.uscfc.uscourts.gov (follow "Go to Announcement Archives" hyperlink; then follow "Chief Judge Emily C. Hewitt announces . . ." hyperlink). Accordingly, although all of her acts in this case pre-dated that elevation, the court refers to Ms. Campbell-Smith by her present title of "Chief Special Master."

[3] The facts, taken primarily from the pleadings and the Chief Special Master's opinion, are undisputed.

blood cells) and antinuclear antibodies ("ANA") (a possible indication of an inflammatory or autoimmune condition, such as rheumatoid arthritis). *Id.* at *10. Suspecting that petitioner had likely experienced an allergic reaction to the vaccines, Dr. Moore directed petitioner to take Benadryl and Tylenol with codeine. *Id.* at *4.

On October 13, 2000, petitioner consulted with Dr. George Gluz. *Id.* Dr. Gluz's examination notes indicate that he too evaluated petitioner for an apparent allergic reaction to hepatitis B and polio vaccines. *Id.* In addition to documenting petitioner's previously reported symptoms of fever, headaches, and tingling, Dr. Gluz noted that petitioner had developed tongue swelling following her second vaccination. *Id.* Dr. Gluz referred petitioner to Dr. Daniel Glor, a neurologist. *Id.*

On October 24, 2000, petitioner presented to Dr. Glor with complaints of pain in her left arm and hand and along the left side of her face. *Id.* at *5. Petitioner reported to Dr. Glor that she had developed a fever on the day of her second vaccination, followed by tongue swelling and headaches over the next few days. *Id.* Petitioner further reported that, as of October 20, she had begun experiencing weakness in her left leg, as well as tingling in her left fingers and toes. *Id.* at *6 n.14. Dr. Glor noted that petitioner had decreased sensation on the left side of her face, but he was unable to assess petitioner's strength on the left side of her body because petitioner's pain apparently prevented her from exerting full effort. *Id.* at *5.

That same day, Dr. Glor admitted petitioner to the hospital. *Id.* At the time of her admission, petitioner had a fever and a slightly elevated count of white blood cells ("WBC"). *Id.* An elevated WBC count is a non-specific finding that can signal infection or inflammation, but, significantly, can also result from emotional trauma or stress. *Id.* During her four-day hospital stay, petitioner underwent extensive diagnostic testing. *Id.* This testing included anatomical scans of petitioner's head and brain using both computed tomography ("CT") and magnetic resonance imaging ("MRI"), as well as an assessment of petitioner's brain function using an electroencephalogram ("EEG"). *Id.* All test results were normal. *Id.* The results of additional blood tests—including ANA levels (which had been slightly elevated two days after petitioner's second vaccination)—were also normal. *Id.* Beyond recommending one final test—a lumbar puncture to test petitioner's cerebrospinal fluid, a test that petitioner refused—petitioner's examining physicians at the hospital suggested that petitioner "might benefit from a psychiatric consultation." *Id.*

When petitioner returned to Dr. Glor on December 13, 2000, she reported that her pain had improved, but that she had fallen three times due to weakness in her left leg. *Id.* Noting "some inconsistencies in [petitioner's] neuro[logical] exam[ination]," Dr. Glor concluded that the "exact etiology of [petitioner's] symptoms [was] unclear." *Id.* So, Dr. Glor referred petitioner to a second neurologist, Dr. Richard Johnson, for further examination. *Id.*

During his examination of petitioner on August 8, 2001, Dr. Johnson noted "the embellished and factitious[4] nature of [petitioner's] physical findings." *Id.* In particular, Dr. Johnson found marked inconsistencies between petitioner's complaints and her behavior during examination. *Id.* For example, although petitioner exhibited "great weakness" along her left side

[4] In medical parlance, a factitious condition is an "artificial" rather than a natural one. *Dorland's Illustrated Medical Dictionary* 682 (31st ed. 2007).

on direct testing, she was able to "hold her hands up in a steady position and [could] move[] the left arm quite well." *Id.* Further, although petitioner "denie[d] any position sense in the hand," her hand "remain[ed] in normal posture with eyes closed." *Id.* As to petitioner's complaint that she did not have "virtually any pain or sensation over the left side of the face," Dr. Johnson noted that "the line of demarcation" of petitioner's reported "anesthesia" (loss of sensation) was "not midline" as would be expected. *Id.* Rather, on testing, petitioner's reported anesthesia "crosse[d] the midline to the normal aesthetic side" (the right side) of her face. *Id.*

Finally, the progression of symptoms that petitioner related to Dr. Johnson diverged markedly from what she had related to Dr. Glor. *Id.* at *6. In particular, petitioner told Dr. Johnson that the onset of numbness (or loss of sensation) on the left side of her body had occurred within twenty minutes of receiving the second vaccination, rather than eighteen days later as she had told Dr. Glor. *Id.* Ultimately, Dr. Johnson concluded that "[a]ll of the major findings [we]re apparently fictitious," and that "the major differential diagnosis would be between hysteria and malingering." *Id.* at *5.

The next day, Dr. Glor admitted petitioner to the hospital for a second time, partly on Dr. Johnson's recommendation that petitioner submit to a lumbar puncture in order "to see if there [was] any underlying problem." *Id.* at *6. During this second hospitalization, petitioner again underwent extensive diagnostic testing, including the recommended lumbar puncture as well as MRI scans of both her brain and spine. *Id.* Again, all test results were normal. *Id.* Petitioner was discharged with a diagnosis of "[p]ossible polyneuropathy/paresthesias,[5] presumably secondary to vaccination," but with a notation by the examining physician that "no documentation of this [diagnosis] ha[d] been made" and that petitioner's symptoms were of "unclear etiology." *Id.*

In September 2001, petitioner returned to see Dr. Glor. *Id.* at *10. At that time, having failed to identify any damage to petitioner's central nervous system, Dr. Glor performed a nerve-conduction study[6] in order to assess whether petitioner's reported symptoms may be traceable to damage in her peripheral nerves. *Id.* The results of the nerve conduction study were normal. *Id.*

Five months later, in February 2002, petitioner returned to the hospital seeking treatment for "burning pain" and a "needle[-]sticking" sensation along the left side of her body. *Id.* at *6 (alteration in original). The examining physician, Dr. Robyn Anderson, noted that, although petitioner would otherwise drag her left foot, petitioner was "able to walk normally when instructed to do so." *Id.* MRI scans of petitioner's brain and spine were all normal, as were the results of all blood tests. *Id.* Describing petitioner's complaints as "bizarre," Dr. Anderson recommended only that petitioner consult a pain clinic for her chronic pain. *Id.*

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[5] Polyneuropathy is a "dysfunction of several or many (esp. peripheral, or sometimes cranial) nerves," Polyneuropathy Definition, Oxford English Dictionary (Mar. 2011), www.oed.com (search "polyneuorpathy"), while paresthesia is "any abnormality of sensory function," including "the abnormal sensation of tingling, numbness, or burning, usually in an extremity," Paresthesia Definition, *supra* (search "paresthesia").

[6] A nerve conduction study assesses the health of peripheral nerves by measuring a nerve's conduction velocity, the speed with which an externally generated electrical impulse (or shock) travels through the nerve fiber; slow conduction velocity may be indicative of nerve damage. *Jarvis*, 2010 WL 5601960, at *10 n.21. The test is acknowledged to be "uncomfortable." *Id.*

In June 2002, petitioner was examined by Dr. Brian Schulman, a psychiatrist and neurologist. *Id.* at *7. Noting "the results of [petitioner's] numerous neurodiagnostic studies, all of which ha[d] failed to reveal any evidence of underlying organic pathology," Dr. Schulman concluded that petitioner's symptoms were "*entirely behavioral, suggestive of a psychogenic reaction*." *Id.* (emphasis in original). In Dr. Schulman's assessment, petitioner's complaints "greatly exceed[ed] any evidence of underlying organic impairment." *Id.* Dr. Schulman thus concluded that petitioner was suffering from a "factitious disorder," *id.*, "a mental disorder characterized by repeated, intentional simulation of physical or psychological signs and symptoms of illness for no apparent purpose other than obtaining treatment,"[7] *id.* at *2 (quoting *Dorland's Illustrated Medical Dictionary* 556 (31st ed. 2007)). Dr. Schulman did not recommend any course of treatment because, he noted, the symptoms of a factitious disorder "do not correlate with any known organic syndrome" and are "not usually amenable to any medical intervention." *Id.* at *7.

Over the next seven months, petitioner returned to see Dr. Glor on three more occasions, the last on January 30, 2003, with no notable change in her reported symptoms. *Id.* Shortly thereafter, petitioner lost her health insurance coverage when her employment was terminated. *Id.* Petitioner then discontinued her treatment with Dr. Glor and has since sought no further medical care for her alleged injury. *Id.*

B. Proceedings Before the Chief Special Master

On February 7, 2003, petitioner filed the petition in this case, claiming that her alleged injury was caused by the hepatitis B vaccination that she received on October 2, 2000. *Id.* at *1. The Vaccine Act authorizes compensation for a "vaccine-related injury," 42 U.S.C. § 300aa-10(a), *i.e.*, an injury caused by a vaccine, and provides two methods by which a petitioner may establish a *prima facie* case of causation. *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1374 (Fed. Cir. 2009); *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). If a petitioner demonstrates that he or she suffered an injury listed in the Vaccine Injury Table, 42 U.S.C. § 300aa-14, and that the injury occurred within a prescribed period of time following receipt of a vaccine also listed therein, the petitioner is said to assert a "table claim" for compensation and the vaccine is presumed to have caused the injury. *Andreu*, 569 F.3d at 1374.

In all other instances—where the alleged injury either is not listed in the Vaccine Injury Table or did not occur within the period of time prescribed therein—the petitioner is said to assert an "off-table" claim and no presumption of causation attaches. *Althen*, 418 F.3d at 1278. Rather, as a threshold matter, the petitioner asserting an off-table claim must prove, by a preponderance of the evidence, the existence of the alleged injury. *Devonshire v. Sec'y of Health & Human Servs.*, 76 Fed. Cl. 452, 454 (2007); *see Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1346, 1349 (Fed. Cir. 2010). Then, in order to establish entitlement to compensation, the off-table petitioner has the burden of proving "causation-in-fact"—*i.e.*, the petitioner must prove, by a preponderance of evidence, "that the vaccine was actually the cause" of the alleged injury. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006); *accord, e.g.*, *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1351 (Fed. Cir. 2008); *Althen*, 418 F.3d at

[7] A factitious disorder "differs from malingering [only] in that there is no recognizable motive for feigning illness." *Jarvis*, 2010 WL 5601960, at *2 (quoting *Dorland's Illustrated Medical Dictionary* 556 (31st ed. 2007)).

1278; *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999); *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1147 (Fed. Cir. 1992).

According to the Federal Circuit in *Althen*, 418 F.3d at 1278, proving "causation-in-fact" turns on satisfying a three-prong test. *Althen* requires the off-table petitioner to show by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* (citing *Grant*, 956 F.2d at 1148). Cumulatively, the evidence offered to satisfy these three prongs must show that the vaccine was not only a "but for" cause of the injury in question, but a "substantial factor" in bringing about that injury. *Id.* (citing *Shyface*, 165 F.3d at 1352 (adopting the "legal cause" standard of the Restatement (Second) of Torts as the standard for proving "causation-in-fact" in Vaccine Act cases)). By making this showing, an off-table petitioner establishes a *prima facie* case of entitlement to compensation. *de Bazan*, 539 F.3d at 1352. Such petitioner is "entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine." *Althen*, 418 F.3d at 1278; *accord, e.g.*, *Andreu*, 569 F.3d at 1375; *de Bazan*, 539 F.3d at 1354.

Throughout, an off-table petitioner's burden of proof is the traditional tort standard of simple preponderance, *i.e.*, proof that it is "more probable than not" that the petitioner in fact suffered a vaccine-related injury. *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010); *Andreu*, 569 F.3d at 1380; *Althen*, 418 F.3d at 1279. Thus, a petitioner need only prove her *prima facie* case to a degree of legal probability, not medical or scientific certainty. *Moberly*, 592 F.3d at 1322; *Andreu*, 569 F.3d at 1380. Of course, a petitioner must demonstrate the reliability of any scientific or other expert evidence put forth to carry this burden. *E.g.*, *Moberly*, 592 F.3d at 1322; *Cedillo ex rel. Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010); *Terran ex rel. Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Expert testimony, in particular, must have some objective scientific basis in order to be credited by the Special Master. *Terran*, 195 F.3d at 1316 (holding that a Special Master may reject expert testimony that is deemed unreliable under the principles set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993)).

Here, petitioner asserts an off-table claim. *Jarvis*, 2010 WL 5601960, at *1. Accordingly, petitioner was required to establish her *prima facie* case by preponderant and reliable evidence, as described above. With that in mind, the Chief Special Master held two hearings, a "fact hearing" aimed at "evaluating the veracity of petitioner's [factual] allegations" of injury, followed by a second hearing devoted to expert testimony. *Id.* at *2. Only two expert witnesses testified at the second hearing, Dr. Carlo Tornatore for petitioner and Dr. Thomas Leist for respondent. *Id.* at *3. Perhaps not surprisingly, the two experts offered wholly divergent assessments of petitioner's alleged injury and its possible etiology. *See id.* at *9–13.

In his written report, Dr. Tornatore initially opined that the hepatitis B vaccination had caused petitioner to suffer an episode of "transverse myelitis"—an immune-mediated inflammation across the width of the spinal cord that can lead to varying degrees of chronic weakness and sensory alterations. *Id.* at *9. Significantly, however, Dr. Tornatore retreated from this diagnosis at the hearing and instead characterized petitioner's alleged injury as "an inflammatory event that caused inflammation in the brain" and thereby resulted in petitioner's alleged symptoms of pain and weakness. *Id.*

Dr. Tornatore supported this assessment by citing petitioner's early symptoms (two days after her second vaccination), including her fever and rash, as well as petitioner's slightly elevated blood levels of bilirubin and ANA (which, as noted above, are possible indications of an inflammatory condition, such as rheumatoid arthritis or inflammation of the red blood cells). *Id.* at *9–10. In Dr. Tornatore's view, these symptoms were all evidence of a "real" inflammatory response to the hepatitis B vaccination. *Id.* at *10. Dr. Tornatore also gave weight to the fact that petitioner's treating physicians had prescribed powerful pain medication, including narcotics (opiates) and other controlled substances that physicians do not prescribe "lightly." *Id.*; Hr'g Tr. at 24–29. Finally, Dr. Tornatore found "most striking" a notation by Dr. Glor that petitioner had "hardly felt the shocks from the [nerve conduction study] machine in her left leg." *Jarvis*, 2010 WL 5601960, at *10.

In further support of his view that petitioner suffers from a genuine neurological injury, Dr. Tornatore challenged one aspect of Dr. Johnson's assessment of petitioner's findings. *Id.* Specifically, Dr. Tornatore testified that petitioner's apparent weakness in turning her head to the left during Dr. Johnson's examination—a finding suggesting a weak sternocloidal mastoid ("SCM")[8] on the right side of the neck—was indeed consistent with petitioner's complaints of weakness along the left side of her body. *Id.* Dr. Tornatore explained that "the right side of the brain . . . moves [the] left arm and leg" but is "also interested in moving [the] head to the left." Hr'g Tr. at 37. As a result, he explained, any abnormality in the right side of the brain would expectedly affect the left arm and leg along with the right SCM. *Jarvis*, 2010 WL 5601960, at *10. Dr. Tornatore stated that Dr. Johnson had thus committed a "kind of rookie error" in counting the apparent weakness of the right SCM among petitioner's factitious findings.[9] *Id.*

[8] The sternocloidal mastoid, or SCM, is the muscle running from just below the ear to the collarbone. *Jarvis*, 2010 WL 5601960, at *10. Perhaps counter-intuitively, it is contraction of the *right* SCM that turns the head to the left, by acting as a lever. *See* Hr'g Tr. at 35.

[9] It appears that the Chief Special Master misunderstood this part of Dr. Tornatore's testimony. *See Jarvis*, 2010 WL 5601960, at *10–11. In her opinion, the Chief Special Master stated that "Dr. Tornatore relied on the results reported in a study filed as Petitioner's Exhibit 45, the Mast[a]glia article," in which patients with lesions in one cerebral hemisphere exhibited weakness when turning their heads away from the affected hemisphere. *Id.* (referring to F.L. Mastaglia et al., *Weakness of Head Turning in Hemiplegia: A Quantitative Study*, 49 J. Neurology, Neurosurgery, and Psychiatry 195–97 (1986)). The Chief Special Master questioned whether Dr. Tornatore's "reliance on the findings in the Mast[a]glia article that involved patients with . . . an existing cerebrovascular lesion was appropriate in this case in which petitioner presented with one-sided weakness in the *absence* of a cerebrovascular lesion." *Id.* at *11 (emphasis added). Yet, a careful reading of the hearing transcript reveals that Dr. Tornatore was not at all relying upon the results of the Mastaglia article, but rather referred to one diagram in the article strictly for illustrative purposes. *See* Hr'g Tr. at 37–38 (referring to "a diagram on the second page" of the Mastaglia article). Dr. Tornatore's substantive point, as clearly illustrated by the referenced diagram, was simply this: as a matter of basic neuroanatomy, nerves originating in the right half of the brain control the *right* SCM along with muscles in the *left* arm and leg. *See id.*; Pet'r's Ex. 45 at 2. Thus, as a result of this basic anatomical fact, an abnormality in the right half of the brain—whether or not the abnormality manifests as a lesion—would lead to weakness in the left limbs but the right SCM. *See* Hr'g Tr. at 34–38.

With respect to a mechanism of causation, Dr. Tornatore opined that the first hepatitis B vaccination "primed" petitioner's immune system, while the second vaccination provided a "boost." *Id.* at *9. In Dr. Tornatore's view, this postulated hyper-activation of petitioner's immune system led to an "inflammatory event" that caused what he hypothesized to be an inflammation in petitioner's brain. *Id.* Dr. Tornatore testified that this "one-time event" was nonetheless sufficient to leave petitioner with "chronic neurologic signs and symptoms." *Id.* Finally, in Dr. Tornatore's view, the timeframe of two to three weeks between petitioner's second vaccination and her development of the alleged neurologic symptoms (weakness and loss of sensation) was "right," *i.e.*, consistent with his theorized mechanism of causation.[10] *Id.*

To be sure, Dr. Tornatore recognized that there were "inconsistencies" in petitioner's medical history, as well as findings that were "difficult to explain" or "recognizably 'f[a]ctitious.'" *Id.* at *11 (alteration in original). Nevertheless, Dr. Tornatore offered that these inconsistencies—which he attributed to possible embellishment or "coincident psychiatric issues"—did not negate the existence of a "bona fide" neurological disorder. Hr'g Tr. at 42–43. Dr. Tornatore also dismissed as "not important" the repeated failure of diagnostic imaging to reveal any inflammatory lesions in petitioner's brain. Hr'g Tr. at 55; *see Jarvis*, 2010 WL 5601960, at *11. In that respect, Dr. Tornatore analogized petitioner's alleged injury to Multiple Sclerosis and Parkinson's disease, disorders where the triggering inflammatory brain lesion may begin to fade after three or four weeks, or where changes in the brain may be "so microscopic" that "the MRI can't see" them. Hr'g Tr. at 55–57.

In sharp contrast, respondent's expert, Dr. Leist, testified that the absence of any detectable lesions in petitioner's brain or spinal cord rendered a neurological injury "very unlikely." *Jarvis*, 2010 WL 5601960, at *13. Dr. Leist was highly skeptical of the timing of petitioner's alleged neurologic symptoms—particularly, petitioner's reports of delirium and "hemianesthesia" (loss of sensation in one half of the body) within twenty minutes of her second vaccination.[11] *Id.* at *12. In Dr. Leist's view, such symptoms could only result from "an immediate onset lesion" either in the brain or "very high up" in the spinal cord. *Id.* Thus, Dr. Leist testified, lesions must be present if a "neurological injury as opposed to [a] psychiatric or psychological state" is to be implicated in petitioner's case. *Id.* at *13.

Dr. Leist did not consider the skepticism of petitioner's treating physicians regarding the veracity of her complaints to be incongruent with their election to prescribe powerful pain medications, including narcotics. *Id.* Dr. Leist explained that, in the absence of any objective measure of a patient's pain, "a physician that takes care of a patient" would "necessarily treat[] pain based on the representations of the patient." *Id.*

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[10] As noted above, petitioner provided different physicians with very different accounts of the timing of her alleged symptoms of tingling and weakness: petitioner told Dr. Johnson that these symptoms began within twenty minutes of her vaccination, but she told Dr. Glor that they began eighteen days later. *See Jarvis*, 2010 WL 5601960, at *6. Dr. Tornatore evidently relied only upon petitioner's account to Dr. Glor. *See id.* at *9.

[11] Conversely to Dr. Tornatore, Dr. Leist evidently relied only upon the records of Dr. Johnson, rather than Dr. Glor, regarding petitioner's account of the timing of these symptoms. *See supra* note 10.

In the final analysis, Dr. Leist concluded that petitioner "did not sustain a vaccine injury or . . . [a] neurologic consequence of the vaccine." *Id.* at *12. Rather, in Dr. Leist's opinion, petitioner's early symptoms (including the rash and tongue swelling) were more consistent with an allergic, rather than a neurologic, reaction to her second vaccination, especially in light of petitioner's documented history of allergic reaction to various medications. *Id.*

C. The Chief Special Master's Decision

Based upon the record as a whole, including the medical history and expert testimony summarized above, the Chief Special Master concluded that petitioner failed to establish that she suffers from a vaccine-related injury. *Id.* at *17. Significantly, deep skepticism as to the existence of petitioner's alleged neurological injury pervaded the Chief Special Master's opinion. *See id.* at *1–3, 14–17. Nevertheless, the Chief Special Master proceeded to apply the *Althen* test for causation. *See id.* at *14–17.

The Chief Special Master credited Dr. Tornatore's unrebutted testimony that "two weeks between a precipitating event—such as the vaccination in th[is] case—and the appearance of an immune-mediated neurological injury falls within the 'right' time frame medically." *Id.* at *17. Accordingly, the Chief Special Master concluded that petitioner established "an appropriate temporal relationship . . . between her vaccination and her alleged injury," thus satisfying the third prong of the *Althen* test. *Id.* However, the Chief Special Master concluded that petitioner failed to satisfy the first two prongs of the *Althen* test. *Id.*

Under the first prong, petitioner needed to establish a medical theory causally connecting her alleged neurological injury to the hepatitis B vaccination. *Althen*, 418 F.3d at 1278. The Chief Special Master cited, *inter alia*, the "lack of any detected evidence of . . . inflammation" in petitioner's brain or spinal cord, as well as the widespread skepticism of petitioner's treating physicians regarding the veracity of her complaints. *Jarvis*, 2010 WL 5601960, at *14–15. In light of this, the Chief Special Master found petitioner's "proffered theory of vaccine-related causation . . . wanting" because it was supported only by Dr. Tornatore's "bare assertion" that "a neurological injury . . . could occur and persist over time with scant evidence of neurological impairment." *Id.* at *15. Accordingly, the Chief Special Master concluded that petitioner failed to satisfy the first *Althen* prong because "the opinion of causation offered by petitioner's expert" did not provide "a scientifically sound and reliable theory of causation." *Id.* (citing, *inter alia*, *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (providing that, under the *Daubert* framework, the trier of fact may reject expert testimony "that is connected to existing data only by the *ipse dixit* of the expert"); *Terran*, 195 F.3d at 1316).

With respect to the second prong of the *Althen* test—which requires a "logical sequence of cause and effect," *Althen*, 418 F.3d at 1278—the Chief Special Master recognized that the results of petitioner's initial blood testing, two days after her second vaccination, were slightly abnormal. *Jarvis*, 2010 WL 5601960, at *16. However, the Chief Special Master juxtaposed "this circumscribed evidence" against the "absence of any other objective evidence" of injury "through either laboratory testing or on magnetic resonance imaging," and against the documented skepticism of petitioner's treating physicians regarding the veracity of her reported symptoms. *Id.* The Chief Special Master concluded that petitioner "failed to establish prong two of *Althen*" because she failed to make "the requisite 'more likely than not' showing . . . that she suffered the

alleged injury." *Id.* at *17. Having thus concluded that petitioner failed to establish a *prima facie* case of entitlement to compensation, the Chief Special Master dismissed the petition. *Id.*

D. Petitioner's Motion for Review

As noted above, petitioner's motion for review recites only one numbered objection to the Chief Special Master's decision. Mot. for Review at 2. Specifically, petitioner asserts that the Chief Special Master unlawfully required petitioner to prove her medical theory of causation (under the first *Althen* prong) to a degree of scientific certainty, rather than by a simple preponderance of the evidence. *Id.* Petitioner argues that she has put forth preponderant evidence of a medical theory of causation through the testimony of Dr. Tornatore, and that the Chief Special Master's refusal to credit that testimony thus amounted to application of an elevated standard of proof. *See id.* at 9–13.

To be sure, petitioner recognizes that the Chief Special Master was entitled to inquire into the reliability of Dr. Tornatore's testimony. *See id.* at 12–13. Petitioner asserts, however, that the Chief Special Master held Dr. Tornatore to a standard of reliability higher than that established by the Supreme Court in *Daubert*. *Id.* at 12. The focus of the *Daubert* reliability inquiry, petitioner notes, "is on principles and methodology, not conclusions." *Id.* (citing *Daubert*, 509 U.S. at 596). In turn, petitioner posits, "Dr. Tornatore's theory [of causation] clearly passes *Daubert* muster" because the "principles and methods" that Dr. Tornatore "used to arrive at his conclusion[s]"—namely, "his experience, his practice, as well as his teaching"—"are accepted and scientifically valid." *Id.* at 13.

Petitioner argues that the Chief Special Master thus impermissibly rejected Dr. Tornatore's proffered theory of causation when she questioned "whether an inflammatory or neurological event could be triggered that still could not be detected in testing and imaging." *Id.* at 9. Noting that the "lack of imaging evidence did not bother" Dr. Tornatore, petitioner argues that the Chief Special Master should have credited Dr. Tornatore's testimony on this point. *Id.* at 12. That testimony, in petitioner's view, sufficed to satisfy her burden under the first prong of the *Althen* test. *Id.* at 13.

In turn, petitioner argues that the combination of evidence satisfying the third and (in her view) first prongs of the *Althen* test logically suffices to satisfy the second prong of the test in her case. *Id.* at 13–14. With this, petitioner concludes that she has established a *prima facie* case of vaccine-related causation under *Althen*. *Id.* at 14. Positing that respondent has failed (or, rather, never attempted) to rebut this *prima facie* case by putting forth evidence of an alternative cause for petitioner's alleged injury, *id.* at 15, petitioner concludes that the Chief Special Master erred in denying compensation, *id.* at 17.

II. STANDARD OF REVIEW

Upon a properly filed motion for review, such as the motion before the court, Section 12(e)(1) of the Vaccine Act grants the court jurisdiction to review the decision of a Special Master. 42 U.S.C. § 300aa-12(e)(1); *see also* Vaccine Rule 23. When conducting this review, the court may embark upon one of three courses of action: (1) uphold the Special Master's findings of fact and conclusions of law; (2) set aside any of the Special Master's findings of fact or conclusions of law found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law; or (3) remand the petition to the

Special Master for further action in accordance with the court's direction. 42 U.S.C. § 300aa-12(e)(2)(A)–(C); *see also* Vaccine Rules 27, 36(b).

Further, the court applies different standards of review to different aspects of a Special Master's decision. *Munn v. Sec'y of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992). The "not in accordance with law" standard applies to a Special Master's conclusions of law. *Id.* This encompasses conclusions stemming from the application of legal standards and burdens of proof. *Doe 93 v. Sec'y of Health & Human Servs.*, 2011 WL 1615238, at *15 (Fed. Cl. 2011); *see Althen*, 418 F.3d at 1277. Under this standard of review, a Special Master's application of law is afforded no deference and is reviewed *de novo*. *Masias v. Sec'y of Health & Human Servs.*, 634 F.3d 1283, 1288 (Fed. Cir. 2011).

By contrast, a Special Master's factual findings are reviewed under the highly deferential "arbitrary and capricious" standard. *Moberly*, 592 F.3d at 1321; *Munn*, 970 F.2d at 870 n.10. Under this standard, reversible error is "extremely difficult to demonstrate" where the Special Master "has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision." *Broekelschen v. Sec'y of Health & Human Servs.*, 68 F.3d 1339, 1348 (Fed. Cir. 2010) (quoting *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

Finally, a Special Master's discretionary rulings are reviewed for "abuse of discretion." *Munn*, 970 F.2d at 870 n.10. Notably, such rulings include determinations regarding the qualification of expert witnesses and the reliability of expert testimony. *Piscopo v. Sec'y of Health & Human Servs.*, 66 Fed. Cl. 49, 53 (2005); *see Joiner*, 522 U.S. at 142–43 (holding that "abuse of discretion is the proper standard of review of a [trial] court's evidentiary rulings," including determinations regarding the reliability of expert testimony under *Daubert*); *Terran*, 195 F.3d at 1316 (reviewing for abuse of discretion the Special Master's decision to reject as unreliable the testimony of the petitioner's expert). Determinations subject to review for abuse of discretion must be sustained unless "manifestly erroneous." *Piscopo*, 66 Fed. Cl. at 53; *see Milmark Servs., Inc. v. United States*, 731 F.2d 855, 860 (Fed. Cir. 1984) (holding that decisions that lie within the trial court's discretion are to be sustained unless "manifestly erroneous").

III. DISCUSSION

Of course, whatever the governing standard, the court's review must be informed by the petitioner's burden of proof. The petitioner asserting an off-table claim, as is the case here, must do the "heavy lifting" of establishing a *prima facie* case by what the Federal Circuit terms a preponderance of the evidence. *Hodges v. Sec'y of Health & Human Servs.*, 9 F.3d 958, 961–62 (Fed. Cir. 1993); *accord Andreu*, 569 F.3d at 1374; *Althen*, 418 F.3d at 1278. Two aspects of this burden warrant further elaboration before the court turns to its review in this case.

A. The Petitioner's Burden in an Off-Table Case

First, "as a prerequisite to proving causation, a petitioner [asserting an off-table claim] must prove by a preponderance of the evidence the existence of the injury she claims was caused by the vaccination." *Devonshire*, 76 Fed. Cl. at 454 (affirming the Special Master's decision to deny compensation on the sole ground that petitioner failed to establish the existence of her alleged injury); *accord Doe 60 v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 597, 624 (2010) (affirming

the Special Master's denial of compensation where the petitioner's experts and treating physicians offered inconsistent diagnoses, none of which was supported by preponderant evidence). In an off-table case, in particular, "identifying the injury is a prerequisite to the [*Althen*] analysis" of causation because "the causation question turns on the determination of the injury." *Broekelschen*, 618 F.3d at 1346. Thus, absent medical records or expert medical opinion substantiating the existence and nature of the alleged injury, "proving causation becomes a moot point." *Devonshire*, 76 Fed. Cl. at 454; *see Broekelschen*, 618 F.3d at 1346 (holding that "it was appropriate for the special master to initially determine which injury [the petitioner] suffered before applying the *Althen* test"). Only if preponderant evidence supports an off-table petitioner's factual allegations of injury does a Special Master need to proceed to apply the *Althen* test for causation. *Devonshire*, 76 Fed. Cl. at 454; *Doe 60*, 94 Fed. Cl. at 624; *see Broekelschen*, 618 F.3d at 1346, 1349.

Through the inquiry under the first *Althen* prong—the nominal target of petitioner's objection in this case, *see infra*—the Special Master must determine whether a petitioner has put forth a "reputable medical theory causally connecting the vaccination and the injury." *Pafford*, 451 F.3d at 1355–56; *accord, e.g.*, *Moberly*, 592 F.3d at 1322; *Althen*, 418 F.3d at 1278. Such theory must take the form of "a reputable medical or scientific explanation that pertains specifically to the petitioner's case." *Broekelschen*, 618 F.3d at 1349; *accord Hennessey v. Sec'y of Health & Human Servs.*, 91 Fed. Cl. 126, 135 (2010) (affirming the Special Master's denial of compensation where the theory of causation posited by petitioner's expert was "so broad as to be meaningless"); *see Althen*, 418 F.3d at 1278 (requiring a "reputable medical or scientific explanation" in the "form of scientific studies or expert medical testimony"). The proffered theory of causation need only be "legally probable, not medically or scientifically certain." *Broekelschen*, 618 F.3d at 1345 (quoting *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548–49 (Fed. Cir. 1994)). Thus, reliable expert opinion testimony setting forth a biologically plausible theory of causation, if unrebutted, is sufficient to satisfy this prong. *See Andreu*, 569 F.3d at 1376; *Althen*, 418 F.3d at 1278–80 (citing *Knudsen*, 35 F.3d at 548–49; *Grant*, 956 F.2d at 1148).

When a petitioner relies upon expert testimony—be it to substantiate the existence of the alleged injury or to establish the requisite causal nexus between the injury and the vaccine—such testimony must rest upon an objective and reliable scientific basis. *Cedillo*, 617 F.3d at 1339; *Moberly*, 592 F.3d at 1324; *Terran*, 195 F.3d at 1316. As the Federal Circuit has noted, by requiring the Special Master to "consider all *relevant and reliable* evidence," Vaccine Rule 8(b)(1) "necessarily contemplates an inquiry into the soundness of scientific" or other expert evidence. *Id.* (emphasis in original). Indeed, for nearly twenty years, the Federal Circuit has made clear that providing objective indicia of the reliability of expert evidence is an integral component of the petitioner's burden in Vaccine Act cases. *See, e.g.*, *Knudsen*, 35 F.3d at 548 (stating that proof of causation in off-table cases "must be supported by a sound and reliable medical or scientific explanation"); *Perreira v. Sec'y of Health & Human Servs.*, 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (noting that "[a]n expert opinion is no better than the soundness of the reasons supporting it" and affirming the Special Master's decision to deny the award of attorney fees after the point in the proceedings when petitioners "no longer had a reasonable basis for claiming causation in-fact because the expert opinion was grounded in neither medical literature nor studies"); *Hodges*, 9 F.3d at 961–62 (affirming the denial of compensation where the Special Master was "simply . . . demanding some degree of acceptable scientific support" for the petitioner's theory of causation and "found that the medical evidence of record failed" to provide such support).

To be sure, the Special Master may not use a reliability inquiry to "cloak"—and thereby shield from *de novo* review—"the application of an erroneous legal standard" such as an elevated burden of proof. *Andreu*, 569 F.3d at 1379. However, as the finder of fact, the Special Master is "entitled—indeed, expected—to make determinations as to the reliability of the evidence presented." *Moberly*, 592 F.3d at 1326; *accord Hazelhurst v. Sec'y of Health & Human Servs.*, 604 F.3d 1343, 1350 (Fed. Cir. 2010) (approving the Court of Federal Claims' observation that the Special Master "was duty-bound to assess the reliability" of the petitioner's evidence). In particular, the Special Master is "entitled to require some indicia of reliability to support the assertion[s] of [an] expert witness." *Moberly*, 592 F.3d at 1324.

The Federal Circuit has held that this reliability inquiry may be appropriately guided by the general principles set forth in *Daubert*. *Cedillo*, 617 F.3d at 1338–39; *Terran*, 195 F.3d at 1316 (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 148 (1999); *Daubert*, 509 U.S. at 592). As the Supreme Court explained in *Daubert*, the specialized "knowledge" that is necessarily the subject of expert testimony requires "more than subjective belief or unsupported speculation" on the expert's part. *Daubert*, 509 U.S. at 590. Thus, expert testimony "must be supported by appropriate validation—*i.e.*, 'good grounds,' based on what is known"—so that "*evidentiary reliability* will be based upon *scientific validity*." *Id.* at 590 n.9. Applying these principles requires the Special Master to determine whether the opinion of an expert witness has "a reliable basis in the knowledge and experience of [the relevant] discipline." *Terran*, 195 F.3d at 1316 (quoting *Kumho Tire*, 526 U.S. at 149).

Of course, the assessment of evidentiary reliability must focus "on principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 595. In practice, however, that focus is not so readily circumscribed because an expert's "conclusions and methodology are not entirely distinct from one another." *Cedillo*, 617 F.3d at 1339 (quoting *Joiner*, 522 U.S. at 146). Accordingly, a Special Master need not credit expert opinion testimony that is connected to the existing data or methodology "only by the *ipse dixit* of the expert," or where "there is simply too great an analytical gap between the data and the opinion proffered." *Id.*

B. Elucidating the Grounds for the Chief Special Master's Decision

With these considerations in mind, the court next turns to ascertaining the true grounds for the Chief Special Master's decision. This case is unusual in that even a cursory review of the evidentiary record, as summarized above, raises serious questions about the very existence of petitioner's alleged injury. *See Jarvis*, 2010 WL 5601960, at *3 (noting the "scant objective evidence of neurologic abnormality"). In light of this, the Chief Special Master began her opinion by identifying "two issues" that were "[i]mportant to [her] evaluation of petitioner's claim of vaccine-related causation." *Id.* at *1. The first issue "involve[d] clarifying the particular condition for which petitioner seeks Program compensation," while the second "involve[d] identifying reliable and objective evidence that petitioner in fact suffers from the alleged condition." *Id.* What followed was an opinion pervaded by deep skepticism regarding the veracity of petitioner's factual allegations of neurological injury. *See id.* at *1–3, 14–17.

Of course, as explained above, establishing the existence of the alleged injury was an integral element of petitioner's *prima facie* case and a prerequisite to the causation inquiry. *See Broekelschen*, 618 F.3d at 1346; *Doe 60*, 94 Fed. Cl. at 624; *Devonshire*, 76 Fed. Cl. at 454. Not surprisingly, therefore, the Chief Special Master's decision turned entirely on her implicit but

unmistakable factual finding that petitioner had failed to establish the existence of her alleged injury. *See id.* at *14–16. In particular, a careful reading of the Chief Special Master's opinion reveals that her application of the *Althen* test involved no analysis of causation at all, but instead focused exclusively on evaluating the evidence in support of petitioner's allegations of injury. *See id.*

In her analysis under the first *Althen* prong—which requires a medical theory of causation—the Chief Special Master began by considering Dr. Tornatore's characterizations of petitioner's alleged injury. *Id.* at *14. The Chief Special Master noted that Dr. Tornatore's initial opinion (in his written report) that petitioner had suffered an episode of transverse myelitis was "a singular one," shared by none of petitioner's treating physicians. *Id.* The Chief Special Master further noted that Dr. Tornatore himself abandoned this opinion at the hearing. *Id.* Accordingly, the Chief Special Master deemed irrelevant petitioner's filed medical literature because it pertained exclusively to transverse myelitis, an injury that "petitioner has not been shown to have." *Id.* at *15.

Next, the Chief Special Master addressed the failure of diagnostic imaging to detect any lesions in petitioner's brain or spinal cord. *Id.* The Chief Special Master cited the testimony of respondent's expert, Dr. Leist, who "challenged the biological mechanism proposed in this case because the medical records do not indicate . . . that petitioner ever developed any lesions." *Id.* The Chief Special Master juxtaposed this against Dr. Tornatore's out-of-hand dismissal of this negative finding and his failure to explain the pertinence of his analogy to Multiple Sclerosis and Parkinson's disease. *Id.* In conclusion, the Chief Special Master stated that petitioner had offered nothing but Dr. Tornatore's "bare assertion" to support "the asserted causal theory that a neurological injury involving intermittent but marked physical limitations on one side of the body could occur and persist over time with scant evidence of neurological impairment." *Id.* at *15. Of course, this portion of Dr. Tornatore's testimony was fundamentally a hypothesis regarding the existence of petitioner's injury, not a "causal theory" as the Chief Special Master labeled it. *See id.*

Similarly, in her analysis under the second *Althen* prong—which requires a logical sequence of cause and effect—the Chief Special Master focused on "the absence of medical evidence to support [petitioner's] persistent neurological complaints." *Id.* at *16. The Chief Special Master explained that, in her assessment, the evidence provided "limited support" for petitioner's claim that she had suffered an inflammatory event affecting her brain. *Id.* The Chief Special Master also noted that petitioner's findings on examination "were strikingly inconsistent with her reported weakness and pain," leading her examiners to "describe[] her alleged condition variously as 'bizarre,' 'embellished,' or 'factitious.'" *Id.* Accordingly, the Chief Special Master found that the evidence in the record "sharply call[s] into question whether petitioner in fact did suffer a neurological injury." *Id.* It is on that basis that the Chief Special Master concluded that petitioner failed to satisfy the second *Althen* prong. *Id.* at *17.

In sum, although the Chief Special Master framed her analysis as a causation inquiry under *Althen*, her decision rested squarely upon the implicit but unmistakable finding that petitioner had failed to prove her factual allegations of neurological injury. In turn, this finding rested largely upon the Chief Special Master's rejection of the testimony of petitioner's expert, Dr. Tornatore. For her part, petitioner recognizes that the Chief Special Master's decision "had little to do with the hepatitis B vaccine" or causation *per se*, and "all to do with whether an inflammatory or neurological event could be triggered that still could not be detected in testing and imaging." Mot.

for Review at 9. Accordingly, the central question presented to the court on review is whether the Chief Special Master made a proper reliability determination when she rejected Dr. Tornatore's testimony regarding the existence and nature of petitioner's alleged injury.

C. The Court's Review

In answering that question, the court finds particularly instructive the Federal Circuit's recent decisions in *Andreu* and *Moberly*. In both cases, the petitioners sought compensation for the same injury (a generalized seizure disorder) and alleged causation by the same vaccine (the Diphtheria-Pertussis-Tetanus, or DPT, vaccine). *Compare Andreu*, 569 F.3d at 1370–71, *with Moberly*, 592 F.3d at 1318–19. In both cases, the petitioners advanced the same theory of causation and relied primarily upon expert testimony to do so. *Compare Andreu*, 569 F.3d at 1377, *with Moberly*, 592 F.3d at 1319–20; *see also Moberly*, 592 F.3d at 1324–26 (comparing and contrasting the facts and evidentiary record in *Moberly* and *Andreu*). And, in each case, the presiding Special Master concluded that the petitioner had failed to establish causation partly on the ground that the testimony of the petitioner's expert was either not reliable or not credible. *Compare Andreu*, 569 F.3d at 1379, *with Moberly*, 592 F.3d at 1320; *also compare Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, No. 98-817V, 2008 WL 2517179, at *7–9 (Fed. Cl. May 29, 2008), *with Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, No. 98-910V, 2005 WL 1793416, at *23–29 (Fed. Cl. June 30, 2005).

On appeal, the Federal Circuit reached divergent decisions in the two cases. In *Andreu*, the Federal Circuit concluded that the petitioner successfully proved causation and that the Special Master had used the garb of reliability and credibility determinations to cloak the application of an elevated burden of proof. *Andreu*, 569 F.3d at 1379. Significantly, this is essentially what petitioner argues the Chief Special Master did in this case. *See* Mot. for Review at 9–13. By contrast, in *Moberly*, the Federal Circuit upheld the Special Master's reliability determination and concluded that the Special Master had applied the correct legal standard. *Moberly*, 592 F.3d at 1324–26.

As the Federal Circuit explained in *Moberly*, these two divergent decisions turned on the "significantly different" evidentiary records in the two cases. *Moberly*, 592 F.3d at 1325. In *Andreu*, "direct testimony from [the petitioner's] treating physicians stat[ed] 'unequivocally' that the DPT inoculation [had] caused his seizures." *Moberly*, 592 F.3d at 1325 (quoting *Andreu*, 569 F.3d at 1376). By contrast, in *Moberly*, the petitioner's "principal treating physician . . . expressed skepticism that [the petitioner's] condition was caused by her DPT vaccination." *Id.* Further, in *Andreu*, the petitioner's theory of causation was uncontested by the government's expert witness, whereas the government's expert in *Moberly* directly challenged the theory's biological plausibility. *Id.* Finally, in *Moberly*, the petitioner's "expert witness undercut his own position by conceding not only that . . . [his] theory [of causation] had never been tested, but also that there was no evidence suggesting that it applied to [the petitioner's] case." *Id.*

To be sure, the subject of the rejected expert testimony in this case is the petitioner's injury, not its causal connection to the vaccine. However, in assessing evidentiary reliability, what matters is the relationship between the expert testimony and the broader evidentiary record. *See, e.g.*, *Joiner*, 522 U.S. at 146 (explaining that the "analytical gap between the data and the opinion proffered" is central to the reliability of expert opinion). In that regard, *Moberly* and *Andreu* are highly instructive for the court's present review.

Just as the petitioner's treating physicians in *Moberly* doubted the possibility of vaccine-related causation, the treating physicians in this case expressed widespread skepticism regarding the veracity of petitioner's reported symptoms. *See Jarvis*, 2010 WL 5601960, at *5–7. In particular, petitioner's physicians stressed the consistent negative findings of her numerous neurodiagnostic tests, and they repeatedly noted inconsistencies between petitioner's complaints and her findings on examination. *See id.* (discussing the inconsistencies noted by at least three treating physicians, including Drs. Glor, Anderson, and Johnson). These included physicians who examined petitioner only once, as well as petitioner's long-term treating physician, Dr. Glor. *Id.* at *5.

Also as in *Moberly*, the testimony of petitioner's expert was directly challenged by respondent's expert, Dr. Leist. *See id.* at *12–13. Dr. Tornatore described petitioner's injury as "an inflammatory event that caused inflammation in the brain." *Id.* at *9. In part, Dr. Tornatore based this opinion upon petitioner's early symptoms, including petitioner's rash and slightly elevated blood levels of bilirubin and ANA. *Id.* at *9–10. In Dr. Tornatore's view, these were all evidence of a "real" inflammatory response. *Id.* Dr. Leist, however, strongly disagreed, testifying that petitioner's early symptoms were more consistent with an allergic reaction to her second vaccination. *Id.* at *12. And Dr. Tornatore offered no basis for his opinion that any inflammatory response experienced by petitioner had exceeded the initial allergic reaction that both Dr. Leist, *id.* at *12, and petitioner's treating physician, Dr. Moore, *id.* at *4, considered more likely.

Also challenged was Dr. Tornatore's opinion that it was "not important" that diagnostic imaging had failed to reveal any evidence of the inflammatory brain lesion that he hypothesized. Hr'g Tr. at 55; *see Jarvis*, 2010 WL 5601960, at *11. The essence of Dr. Tornatore's testimony on this point was that the absence of a detectable lesion in petitioner's brain did not disprove the existence of microscopic changes in petitioner's brain or negate the possibility of a temporary lesion that had completely faded before petitioner's first MRI. *See* Hr'g Tr. at 55–57 (analogizing to Parkinson's disease and Multiple Sclerosis). To the contrary, Dr. Leist testified that lesions must be present if a "neurological injury as opposed to [a] psychiatric or psychological state" was to be implicated in petitioner's case. *Jarvis*, 2010 WL 5601960, at *13. In Dr. Leist's expert opinion, the absence of any such lesions in petitioner's brain or spinal cord rendered a neurological injury "very unlikely." *Id.* at *13.

Finally, much like the petitioner's expert in *Moberly*, Dr. Tornatore undercut his own testimony when he conceded that many of petitioner's findings were recognizably "fictitious" and possibly attributable to "coincident psychiatric issues." Hr'g Tr. at 39–40, 42–43. Perhaps in an attempt to offset this concession, Dr. Tornatore made much of refuting Dr. Johnson's conclusion that the apparent weakness in petitioner's right SCM muscle was inconsistent with her other complaints. *See id.* at 34–38; *Jarvis*, 2010 WL 5601960, at *10. However, Dr. Tornatore did not refute the many other "factitious findings" identified by Dr. Johnson, *see* Pet'r's Ex. 17 at 189, findings that collectively led the latter to conclude that petitioner was either hysterical or malingering, *id.* at 191.

Beyond these similarities to the evidentiary record in *Moberly*—a record that led the Federal Circuit to uphold the Special Master's determination that the expert's testimony was unreliable—the filed medical records in this case all but support the negative inference that petitioner does not suffer from *any* physiological disorder. As recounted above, the results of all diagnostic testing to which petitioner submitted—over the course of nearly eighteen months and

through three hospital stays—were consistently normal. *Jarvis*, 2010 WL 5601960, at *4–7. Thus, the record is devoid of any objective evidence of the neurological injury for which petitioner seeks compensation.

Most compelling, perhaps, are the assessments of Drs. Johnson and Schulman, who independently concluded that petitioner's complaints were entirely fictitious and were most likely attributable to a psychiatric condition. *See id.* at *5–7. As noted above, Dr. Johnson, whom petitioner's own expert described as a "towering figure in neurology," *id.* at *11, concluded that "the major differential diagnosis would be between hysteria and malingering," *id.* at *5. Dr. Schulman—who, significantly, is both a neurologist and a psychiatrist—was more decided in his conclusions. *Id.* at *7. Dr. Schulman's ultimate diagnosis was that petitioner suffers, not from any neurological injury, but from a factitious disorder—a psychiatric condition that led petitioner to *simulate* physical signs and symptoms merely for the purpose of obtaining treatment. *Id.*

In sum, Dr. Tornatore's opinion that petitioner had suffered an inflammatory brain lesion that was too small or too short-lived to be detected by diagnostic imaging left the Chief Special Master with nothing but Dr. Tornatore's *ipse dixit* that the hypothesized injury ever occurred. *See Joiner*, 522 U.S. at 146 (explaining that nothing in *Daubert* requires the trier of fact "to admit [or deem reliable] opinion evidence that is connected to existing data only by the *ipse dixit* of the expert"). In the final analysis, therefore, the Chief Special Master was left with an evidentiary record devoid of any objective indicia—good grounds, based on what is actually known of petitioner's condition—of the reliability of Dr. Tornatore's testimony. *See Daubert*, 509 U.S. at 590; *Moberly*, 592 F.3d at 1324.

Accordingly, the court concludes that the Chief Special Master reasonably exercised her broad discretion in determining the reliability of expert testimony when she rejected Dr. Tornatore's testimony on this point. *See Kumho Tire*, 526 U.S. at 152 (describing the "broad latitude" that the trier of fact enjoys "in deciding *how* to test an expert's reliability" as well as "*whether or not* that expert's relevant testimony is reliable"); *Terran*, 195 F.3d at 1316 (reviewing the Special Master's reliability determination for abuse of discretion). In turn, the Chief Special Master found—based upon a thorough review of all other evidence—that petitioner had failed to prove that she ever suffered the neurological injury for which she seeks compensation. *See Broekelschen*, 68 F.3d at 1348 (explaining that the Special Master need only "consider[] the relevant evidence of record, draw[] plausible inferences and articulate[] a rational basis" for her findings of fact). The court concludes that this finding was both reasonable and virtually inescapable in light of the evidence in this case.

Of course, as already alluded, petitioner contends otherwise. Specifically, petitioner objects that the Chief Special Master unlawfully required Dr. Tornatore to substantiate his testimony to a degree of scientific certainty. Mot. for Review at 2 (citing *Althen*, 418 F.3d at 1278). Petitioner's central argument in support of this objection proceeds as follows.

First, petitioner correctly notes that Dr. Tornatore need not have demonstrated that his conclusions are accepted in the medical community, only that the principles and methodology he used are scientifically valid. *Id.* at 12 (citing *Daubert*, 509 U.S. at 594). Next, petitioner acknowledges that establishing scientific validity requires "some objective source—a learned treatise, the policy statement of a professional association, a published article in a reputable scientific journal or the like." *Id.* at 12–13. Petitioner then concludes, "Dr. Tornatore testified

extensively that in his experience, his practice, as well as his teaching that an inflammatory/neurological injury can occur without evidence showing up in an MRI. His principles and methods used to arrive at his conclusion are accepted and scientifically valid. Dr. Tornatore's theory clearly passes *Daubert* muster in this regard." *Id.* at 13.

Conspicuously absent from petitioner's argument, however, is a citation to anything in the record that would constitute the kind of "objective source" of scientific validity that petitioner acknowledges was required. *See id.* at 12–13. More importantly, the proposition that a neurological injury *can* occur "without evidence showing up in an MRI," *id.* at 13—even if such proposition had been substantiated—does not prove that such an injury *did* occur in petitioner's case. As discussed at length above, what is fatal to petitioner's case is her failure to make that fundamental showing. The remainder of petitioner's memorandum in support of her motion for review is largely devoted to reiterating (several times) Dr. Tornatore's testimony and the limited portions of petitioner's medical history on which he focused. *See id.* at 5–6, 8–9, 11, 15–16. Yet petitioner cannot hope to substantiate the bare assertions of her expert through sheer repetition or conclusory assertions of her own.

Given the lack of any objective basis for Dr. Tornatore's opinion testimony, the Chief Special Master correctly applied basic principles of evidentiary reliability when she discounted this expert's bare assertions. *See Joiner*, 522 U.S. at 146; *Daubert*, 509 U.S. at 590; *Moberly*, 592 F.3d at 1324. And, although the Chief Special Master need not have applied the *Althen* test, she properly considered all relevant evidence and articulated a rational basis for her decision. *See Broekelschen*, 68 F.3d at 1348 (noting that reversible error is "extremely difficult to demonstrate" where the Special Master "has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision"). The unmistakable basis for the Chief Special Master's decision was her finding, as the trier of fact, that petitioner failed to establish the existence of the neurological injury for which she seeks compensation. As discussed above, that finding was all but inescapable in this case. Accordingly, the court can find nothing in the Chief Special Master's decision that was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

IV. CONCLUSION

For the foregoing reasons, the Chief Special Master's decision is AFFIRMED and the petition is DISMISSED with prejudice.

IT IS SO ORDERED.

s/ *Lawrence J. Block*
Lawrence J. Block
Judge